

103D CONGRESS
1ST SESSION

S. 1658

To establish safe harbors from the application of the antitrust laws for certain activities of providers of health care services, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 10 (legislative day, NOVEMBER 2), 1993

Mr. HATCH (for himself and Mr. THURMOND) introduced the following bill;
which was read twice and referred to the Committee on the Judiciary

A BILL

To establish safe harbors from the application of the anti-trust laws for certain activities of providers of health care services, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the “Health Care Antitrust
5 Improvements Act of 1993”.

1 **SEC. 2. EXEMPTION FROM ANTITRUST LAWS FOR CERTAIN**
2 **COMPETITIVE AND COLLABORATIVE ACTIVITIES.**
3

4 (a) **EXEMPTION DESCRIBED.**—An activity relating to
5 the provision of health care services shall be exempt from
6 the antitrust laws if—

7 (1) the activity is within one of the categories
8 of safe harbors described in section 3;

9 (2) the activity is within an additional safe har-
10 bor designated by the Attorney General under sec-
11 tion 4; or

12 (3) the activity is specified in and in compliance
13 with the terms of a certificate of review issued by
14 the Attorney General under section 5 and the activ-
15 ity occurs—

16 (A) while the certificate is in effect, or

17 (B) in the case of a certificate issued dur-
18 ing the 2-year period beginning on the date of
19 the enactment of this Act, at any time on or
20 after the first day of the 2-year period that
21 ends on the date the certificate takes effect.

22 (b) **AWARD OF ATTORNEY'S FEES AND COSTS OF**
23 **SUIT.**—

24 (1) **IN GENERAL.**—If any person brings an ac-
25 tion alleging a claim under the antitrust laws and
26 the activity on which the claim is based is found by

the court to be exempt from such laws under subsection (a), the court shall, at the conclusion of the action—

(A) award to a substantially prevailing claimant the cost of suit attributable to such claim, including a reasonable attorney's fee, or

(B) award to a substantially prevailing party defending against such claim the cost of such suit attributable to such claim, including reasonable attorney's fee, if the claim, or the claimant's conduct during litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith.

(2) OFFSET IN CASES OF BAD FAITH.—The court may reduce an award made pursuant to paragraph (1) in whole or in part by an award in favor of another party for any part of the cost of suit (including a reasonable attorney's fee) attributable to conduct during the litigation by any prevailing party that the court finds to be frivolous, unreasonable, without foundation, or in bad faith.

SEC. 3. SAFE HARBORS.

The following activities are safe harbors for purposes of section 2(a)(1):

1 (1) COMBINATIONS WITH MARKET SHARE
2 BELOW THRESHOLD.—Activities relating to health
3 care services of any combination of health care pro-
4 viders if the number of each type or specialty of pro-
5 vider in question does not exceed 20 percent of the
6 total number of such type or specialty of provider in
7 the relevant market area.

8 (2) ACTIVITIES OF MEDICAL SELF-REGULATORY
9 ENTITIES.—

10 (A) IN GENERAL.—Subject to subpara-
11 graph (B), any activity of a medical self-regu-
12 latory entity relating to standard setting or
13 standard enforcement activities that are de-
14 signed to promote the quality of health care
15 provided to patients.

16 (B) EXCEPTION.—No activity of a medical
17 self-regulatory entity may be deemed to fall
18 under the safe harbor established under this
19 paragraph if the activity is conducted for pur-
20 poses of financial gain.

21 (3) PARTICIPATION IN SURVEYS.—The partici-
22 pation of a provider of health care services in a writ-
23 ten survey of the prices of services, reimbursement
24 levels, or the compensation and benefits of employ-
25 ees and personnel, but only if—

(A) the survey is conducted by a third party, such as a purchaser of health care services, governmental entity, institution of higher education, or trade association;

(B) the information provided by participants in the survey is based on prices charged, reimbursements received, or compensation and benefits paid prior to the third month preceding the month in which the information is provided; and

(C) if the results of the survey are disseminated, the results are aggregated in a manner that ensures that no recipient of the results may identify the prices charged, reimbursement received, or compensation and benefits paid by any particular provider.

(4) JOINT VENTURES FOR HIGH TECHNOLOGY AND COSTLY EQUIPMENT AND SERVICES.—Any activity of a health care cooperative venture relating to the purchase, operation, or marketing of high technology or other expensive medical equipment, or the provision of high cost or complex services, but only if the number of participants in the venture does not exceed the lowest number needed to support the venture. Other providers may be included in the ven-

1 ture, but only if such other providers could not pur-
2 chase, operate, or market such equipment or provide
3 a competing service either alone or through the for-
4 mation of a competing venture.

5 (5) HOSPITAL MERGERS.—Activities relating to
6 a merger of 2 hospitals if, during the 3-year period
7 preceding the merger, one of the hospitals had an
8 average of 150 or fewer operational beds and an av-
9 erage daily inpatient census of less than 50 percent
10 of such beds.

11 (6) JOINT PURCHASING ARRANGEMENTS.—Any
12 joint purchasing arrangement among health care
13 providers if—

14 (A) the purchases under the arrangement
15 represent less than 35 percent of the total sales
16 of the product or service purchased in the rel-
17 evant market; and

18 (B) the cost of the products and services
19 purchased jointly accounts for less than 20 per-
20 cent of the total revenues from all products or
21 services sold by each participant in the joint
22 purchasing arrangement.

23 (7) NEGOTIATIONS.—Activities consisting of
24 good faith negotiations to carry out any activity—

25 (A) described in this section,

1 (B) within an additional safe harbor des-
2 ignated by the Attorney General under section
3 4,

4 (C) that is the subject of an application for
5 a certificate of review under section 5, or

6 (D) that is deemed a submission of a noti-
7 fication under section 6(a)(2)(B),

8 without regard to whether such an activity is carried
9 out.

10 **SEC. 4. DESIGNATION OF ADDITIONAL SAFE HARBORS.**

11 (a) IN GENERAL.—

12 (1) SOLICITATION OF PROPOSALS.—Not later
13 than 30 days after the date of the enactment of this
14 Act, the Attorney General shall publish a notice in
15 the Federal Register soliciting proposals for addi-
16 tional safe harbors.

17 (2) REVIEW AND REPORT ON PROPOSED SAFE
18 HARBORS.—Not later than 180 days after the date
19 of the enactment of this Act, the Attorney General
20 (in consultation with the Secretary of Health and
21 Human Services and the Chair of the Federal Trade
22 Commission) shall—

23 (A) review the proposed safe harbors sub-
24 mitted under paragraph (1); and

1 (B) submit a report to Congress describing
2 the proposals to be included in the publication
3 of additional safe harbors described in para-
4 graph (3) and the proposals that are not to be
5 so included, together with explanations there-
6 fore.

7 (3) PUBLICATION OF ADDITIONAL SAFE HAR-
8 BORS.—Not later than 180 days after the date of
9 the enactment of this Act, the Attorney General (in
10 consultation with the Secretary of Health and
11 Human Services and the Chair of the Federal Trade
12 Commission) shall publish in the Federal Register
13 proposed additional safe harbors for purposes of sec-
14 tion 2(a)(2) for providers of health care services.
15 Not later than 180 days after publishing such pro-
16 posed safe harbors in the Federal Register, the At-
17 torney General shall issue final rules establishing
18 such safe harbors.

19 (b) CRITERIA FOR SAFE HARBORS.—In establishing
20 safe harbors under subsection (a), the Attorney General
21 shall take into account the following:

22 (1) The extent to which a competitive or col-
23 laborative activity will accomplish any of the follow-
24 ing:

1 (A) An increase in access to health care
2 services.

3 (B) The enhancement of the quality of
4 health care services.

5 (C) The establishment of cost efficiencies
6 that will be passed on to consumers, including
7 economies of scale and reduced transaction and
8 administrative costs.

9 (D) An increase in the ability of health
10 care facilities to provide services in medically
11 underserved areas or to medically underserved
12 populations.

13 (E) An improvement in the utilization of
14 health care resources or the reduction in the in-
15 efficient duplication of the use of such re-
16 sources.

17 (2) Whether the designation of an activity as a
18 safe harbor under subsection (a) will result in the
19 following outcomes:

20 (A) Health plans and other health care in-
21 surers, consumers of health care services, and
22 health care providers will be better able to ne-
23 gotiate payment and service arrangements
24 which will reduce costs to consumers.

1 (B) Taking into consideration the charac-
2 teristics of the particular purchasers and pro-
3 viders involved, competition will not be unduly
4 restricted.

5 (C) Equally efficient and less restrictive al-
6 ternatives do not exist to meet the criteria de-
7 scribed in paragraph (1).

8 (D) The activity will not unreasonably
9 foreclose competition by denying competitors a
10 necessary element of competition.

11 **SEC. 5. CERTIFICATES OF REVIEW.**

12 (a) ESTABLISHMENT OF PROGRAM.—In consultation
13 with the Secretary and the Chair, the Attorney General
14 shall (not later than 180 days after the date of the enact-
15 ment of this Act) issue certificates of review in accordance
16 with this section for providers of health care services and
17 advise and assist any person with respect to applying for
18 such a certificate of review.

19 (b) PROCEDURES FOR APPLICATION FOR CERTIFI-
20 CATE.—

21 (1) FORM; CONTENT.—To apply for a certifi-
22 cate of review, a person shall submit to the Attorney
23 General a written application which—

24 (A) specifies the activities relating to the
25 provision of health care services which satisfy

1 the criteria described in section 4(b) and which
2 will be included in the certificate; and

3 (B) is in a form and contains any informa-
4 tion, including information pertaining to the
5 overall market in which the applicant operates,
6 required by rule or regulation promulgated
7 under section 8.

8 (2) PUBLICATION OF NOTICE IN FEDERAL REG-
9 ISTER.—Within 10 days after an application submit-
10 ted under paragraph (1) is received by the Attorney
11 General, the Attorney General shall publish in the
12 Federal Register a notice that announces that an
13 application for a certificate of review has been sub-
14 mitted, identifies each person submitting the appli-
15 cation, and describes the conduct for which the ap-
16 plication is submitted.

17 (3) ESTABLISHMENT OF PROCEDURES FOR IS-
18 SUANCE OF CERTIFICATE.—In consultation with the
19 Chair and the Secretary, the Attorney General shall
20 establish procedures to be used in applying for and
21 in determining whether to approve an application for
22 a certificate of review under this title. Under such
23 procedures the Attorney General shall approve an
24 application if the Attorney General determines that
25 the activities to be covered under the certificate will

1 satisfy the criteria described in section 4(b) for addi-
2 tional safe harbors designated under such section
3 and that the benefits of the issuance of the certifi-
4 cate will outweigh any disadvantages that may result
5 from reduced competition.

6 (4) TIMING FOR DECISION ON APPLICATION.—

7 (A) IN GENERAL.—Within 90 days after
8 the Attorney General receives an application for
9 a certificate of review, the Attorney General
10 shall determine whether the applicant's health
11 care market activities are in accordance with
12 the procedures described in paragraph (3). If
13 the Attorney General, with the concurrence of
14 the Secretary, determines that such procedures
15 are met, the Attorney General shall issue to the
16 applicant a certificate of review. The certificate
17 of review shall specify—

18 (i) the health care market activities to
19 which the certificate applies,

20 (ii) the person to whom the certificate
21 of review is issued, and

22 (iii) any terms and conditions the At-
23 torney General or the Secretary deems nec-
24 essary to assure compliance with the appli-

1 cable procedures described in paragraph
2 (3).

3 (B) APPLICATIONS DEEMED APPROVED.—

4 If the Attorney General does not reject an ap-
5 plication before the expiration of the 90-day pe-
6 riod beginning on the date the Attorney General
7 receives the application, the Attorney General
8 shall be deemed to have approved the applica-
9 tion and to have issued a certificate of review
10 relating to the applicant's health care market
11 activities covered under the application.

12 (5) EXPEDITED ACTION.—If the applicant indi-
13 cates a special need for prompt disposition, the At-
14 torney General and the Secretary may expedite ac-
15 tion on the application, except that no certificate of
16 review may be issued within 30 days of publication
17 of notice in the Federal Register under subsection
18 (b)(2).

19 (6) ACTIONS UPON DENIAL.—

20 (A) NOTIFICATION.—If the Attorney Gen-
21 eral denies in whole or in part an application
22 for a certificate, the Attorney General shall no-
23 tify the applicant of the Attorney General's de-
24 termination and the reasons for it.

1 (B) REQUEST FOR RECONSIDERATION.—

2 An applicant may, within 30 days of receipt of
3 notification that the application has been denied
4 in whole or in part, request the Attorney Gen-
5 eral to reconsider the determination. The Attor-
6 ney General, with the concurrence of the Sec-
7 retary, shall notify the applicant of the deter-
8 mination upon reconsideration within 30 days
9 of receipt of the request.

10 (C) RETURN OF DOCUMENTS.—If the At-
11 torney General denies an application for the is-
12 suance of a certificate of review and thereafter
13 receives from the applicant a request for the re-
14 turn of documents submitted by the applicant
15 in connection with the application for the cer-
16 tificate, the Attorney General and the Secretary
17 shall return to the applicant, not later than 30
18 days after receipt of the request, the documents
19 and all copies of the documents available to the
20 Attorney General and the Secretary, except to
21 the extent that the information has been made
22 public under an exception to the rule against
23 public disclosure described in subsection
24 (g)(2)(B).

1 (7) FRAUDULENT PROCUREMENT.—A certifi-
2 cate of review shall be void ab initio with respect to
3 any health care market activities for which the cer-
4 tificate was procured by fraud.

5 (c) AMENDMENT AND REVOCATION OF CERTIFI-
6 CATES.—

7 (1) NOTIFICATION OF CHANGES.—Any appli-
8 cant who receives a certificate of review—

9 (A) shall promptly report to the Attorney
10 General any change relevant to the matters
11 specified in the certificate; and

12 (B) may submit to the Attorney General
13 an application to amend the certificate to re-
14 flect the effect of the change on the conduct
15 specified in the certificate.

16 (2) AMENDMENT TO CERTIFICATE.—An appli-
17 cation for an amendment to a certificate of review
18 shall be treated as an application for the issuance of
19 a certificate. The effective date of an amendment
20 shall be the date on which the application for the
21 amendment is submitted to the Attorney General.

22 (3) REVOCATION.—

23 (A) GROUNDS FOR REVOCATION.—In ac-
24 cordance with this paragraph, the Attorney
25 General may revoke in whole or in part a cer-

1 tificate of review issued under this section. The
2 following shall be considered grounds for the
3 revocation of a certificate:

4 (i) After the expiration of the 2-year
5 period beginning on the date a person's
6 certificate is issued, the activities of the
7 person have not substantially accomplished
8 the purposes for the issuance of the certifi-
9 cate.

10 (ii) The person has failed to comply
11 with any of the terms or conditions im-
12 posed under the certificate by the Attorney
13 General or the Secretary under subsection
14 (b)(4).

15 (iii) The activities covered under the
16 certificate no longer satisfy the criteria set
17 forth in section 4(b).

18 (B) REQUEST FOR COMPLIANCE INFORMA-
19 TION.—If the Attorney General or Secretary
20 has reason to believe that any of the grounds
21 for revocation of a certificate of review de-
22 scribed in subparagraph (A) may apply to a
23 person holding the certificate, the Attorney
24 General shall request such information from
25 such person as the Attorney General or the Sec-

1 retary deems necessary to resolve the matter of
2 compliance. Failure to comply with such request
3 shall be grounds for revocation of the certificate
4 under this paragraph.

5 (C) PROCEDURES FOR REVOCATION.—If
6 the Attorney General or the Secretary deter-
7 mines that any of the grounds for revocation of
8 a certificate of review described in subpara-
9 graph (A) apply to a person holding the certifi-
10 cate, or that such person has failed to comply
11 with a request made under subparagraph (B),
12 the Attorney General shall give written notice of
13 the determination to such person. The notice
14 shall include a statement of the circumstances
15 underlying, and the reasons in support of, the
16 determination. In the 60-day period beginning
17 30 days after the notice is given, the Attorney
18 General shall revoke the certificate or modify it
19 as the Attorney General or the Secretary deems
20 necessary to cause the certificate to apply only
21 to activities that meet the procedures for the is-
22 suanance of certificates described in subsection
23 (b)(2).

24 (D) INVESTIGATION AUTHORITY.—For
25 purposes of carrying out this paragraph, the

1 Attorney General may conduct investigations in
2 the same manner as the Attorney General con-
3 ducts investigations under section 3 of the Anti-
4 trust Civil Process Act, except that no civil in-
5 vestigative demand may be issued to a person
6 to whom a certificate of review is issued if such
7 person is the target of such investigation.

8 (d) REVIEW OF DETERMINATIONS.—

9 (1) AVAILABILITY OF REVIEW FOR CERTAIN AC-
10 TIONS.—If the Attorney General denies, in whole or
11 in part, an application for a certificate of review or
12 for an amendment to a certificate, or revokes or
13 modifies a certificate pursuant to paragraph (3), the
14 applicant or certificate holder (as the case may be)
15 may, within 30 days of the denial or revocation,
16 bring an action in any appropriate district court of
17 the United States to set aside the determination on
18 the ground that such determination is erroneous
19 based on the preponderance of the evidence.

20 (2) NO OTHER REVIEW PERMITTED.—Except
21 as provided in paragraph (1), no action by the At-
22 torney General or the Secretary pursuant to this
23 title shall be subject to judicial review.

24 (3) EFFECT OF REJECTED APPLICATION.—If
25 the Attorney General denies, in whole or in part, an

1 application for a certificate of review or for an
2 amendment to a certificate, or revokes or amends a
3 certificate, neither the negative determination nor
4 the statement of reasons therefore shall be admissi-
5 ble in evidence, in any administrative or judicial pro-
6 ceeding, concerning any claim under the antitrust
7 laws.

8 (e) PUBLICATION OF DECISIONS.—The Attorney
9 General shall publish a notice in the Federal Register on
10 a timely basis of each decision made with respect to an
11 application for a certificate of review under this section
12 or the amendment or revocation of such a certificate, in
13 a manner that protects the confidentiality of any propri-
14 etary information relating to the application.

15 (f) ANNUAL REPORTS.—Every person to whom a cer-
16 tificate of review is issued shall submit to the Attorney
17 General an annual report, in such form and at such time
18 as the Attorney General may require, that contains any
19 necessary updates to the information required under sub-
20 section (b) and a description of the activities of the holder
21 under the certificate during the preceding year.

22 (g) RESTRICTIONS ON DISCLOSURE OF INFORMA-
23 TION.—

24 (1) WAIVER OF DISCLOSURE REQUIREMENTS
25 UNDER ADMINISTRATIVE PROCEDURE ACT.—Infor-

1 mation submitted by any person in connection with
2 the issuance, amendment, or revocation of a certifi-
3 cate of review shall be exempt from disclosure under
4 section 552 of title 5, United States Code.

5 (2) RESTRICTIONS ON DISCLOSURE OF COM-
6 MERCIAL OR FINANCIAL INFORMATION.—

7 (A) IN GENERAL.—Except as provided in
8 subparagraph (B), no officer or employee of the
9 United States shall disclose commercial or fi-
10 nancial information submitted in connection
11 with the issuance, amendment, or revocation of
12 a certificate of review if the information is priv-
13 ileged or confidential and if disclosure of the in-
14 formation would cause harm to the person who
15 submitted the information.

16 (B) EXCEPTIONS.—Subparagraph (A)
17 shall not apply with respect to information
18 disclosed—

19 (i) upon a request made by the Con-
20 gress or any committee of the Congress,

21 (ii) in a judicial or administrative pro-
22 ceeding, subject to appropriate protective
23 orders,

24 (iii) with the consent of the person
25 who submitted the information,

(iv) in the course of making a determination with respect to the issuance, amendment, or revocation of a certificate of review, if the Attorney General deems disclosure of the information to be necessary in connection with making the determination,

(v) in accordance with any requirement imposed by a statute of the United States, or

(vi) in accordance with any rule or regulation promulgated under subsection (i) permitting the disclosure of the information to an agency of the United States or of a State on the condition that the agency will disclose the information only under the circumstances specified in clauses (i) through (v).

(3) PROHIBITION AGAINST USE OF INFORMATION TO SUPPORT OR ANSWER CLAIMS UNDER ANTI-TRUST LAWS.—Any information disclosed in an application for a certificate of review under this section shall only be admissible into evidence in a judicial or administrative proceeding for the sole purpose of es-

1 tablishing that a person is entitled to the protections
2 provided by such a certificate.

3 **SEC. 6. NOTIFICATIONS PROVIDING REDUCTION IN CER-**
4 **TAIN PENALTIES UNDER ANTITRUST LAW**
5 **FOR HEALTH CARE COOPERATIVE VEN-**
6 **TURES.**

7 (a) NOTIFICATIONS DESCRIBED.—

8 (1) SUBMISSION OF NOTIFICATION BY VEN-
9 TURE.—Any party to a health care cooperative ven-
10 ture, acting on such venture's behalf, may, not later
11 than 90 days after entering into a written agreement
12 to form such venture or not later than 90 days after
13 the date of the enactment of this Act, whichever is
14 later, file with the Attorney General a written notifi-
15 cation disclosing—

16 (A) the identities of the parties to such
17 venture,

18 (B) the nature and objectives of such ven-
19 ture, and

20 (C) such additional information as the At-
21 torney General may require by regulation.

22 (2) ACTIVITIES DEEMED SUBMISSION OF NOTI-
23 FICATION.—The following health care cooperative
24 ventures shall be deemed to have filed a written noti-

1 fication with respect to the venture under paragraph
2 (1):

3 (A) SUBMISSION OF APPLICATION FOR
4 CERTIFICATE OF REVIEW.—Any health care co-
5 operative venture for which an application for a
6 certificate of review is filed with the Attorney
7 General under section 4.

8 (B) CERTAIN VENTURES.—Any health care
9 cooperative venture meeting the following re-
10 quirements:

11 (i) The venture consists of a network
12 of non-institutional providers not greater
13 than—

14 (I) in the case of a nonexclusive
15 network in which the participating
16 members are permitted to create or
17 join other competing networks, 50
18 percent of the providers of health care
19 services in the relevant geographic
20 area and 50 percent of the members
21 of the provider specialty group in the
22 relevant market; or

23 (II) in the case of an exclusive
24 network in which the participating
25 members are not permitted to create

1 or join other competing networks, 35
2 percent of the providers of health care
3 services in the relevant geographic
4 area and 35 percent of the members
5 of the provider specialty group in the
6 relevant market.

7 (ii) Each member of the venture as-
8 sumes substantial financial risk for the op-
9 eration of the venture through risk-sharing
10 arrangements, including (but not limited
11 to)—

12 (I) the acceptance of capitation
13 contracts;

14 (II) the acceptance of contracts
15 with fee withholding mechanisms re-
16 lating to the ability to meet estab-
17 lished goals for utilization review and
18 management; and

19 (III) the holding by members of
20 significant ownership or equity inter-
21 ests in the venture, where the capital
22 contributed by the members is used to
23 fund the operational costs of the ven-
24 ture such as administration, market-
25 ing, and computer-operated medical

1 information, if the venture develops
2 and operates comprehensive programs
3 for utilization management and qual-
4 ity assurance that include controls
5 over the use of institutional, special-
6 ized, and ancillary medical services.

7 (3) SUBMISSION OF ADDITIONAL INFORMA-
8 TION.—

9 (A) REQUEST OF ATTORNEY GENERAL.—

10 At any time after receiving a notification filed
11 under paragraph (1), the Attorney General may
12 require the submission of additional information
13 or documentary material relevant to the pro-
14 posed health care cooperative venture.

15 (B) PARTIES TO VENTURE.—Any party to
16 a health care cooperative venture may submit
17 such additional information on the venture's be-
18 half as may be appropriate to ensure that the
19 venture will receive the protections provided
20 under subsection (b).

21 (C) REQUIRED SUBMISSION OF INFORMA-
22 TION ON CHANGES TO VENTURE.—A health
23 care cooperative venture for which a notification
24 is in effect under this section shall submit infor-
25 mation on any change in the membership of the

1 venture not later than 90 days after such
2 change occurs.

3 (4) PUBLICATION OF NOTIFICATION.—

4 (A) INFORMATION MADE PUBLICLY AVAIL-
5 ABLE.—Not later than 30 days after receiving
6 a notification with respect to a venture under
7 paragraph (1), the Attorney General shall pub-
8 lish in the Federal Register a notice with re-
9 spect to the venture that identifies the parties
10 to the venture and generally describes the pur-
11 pose and planned activity of the venture. Prior
12 to its publication, the contents of the notice
13 shall be made available to the parties to the
14 venture.

15 (B) RESTRICTION ON DISCLOSURE OF
16 OTHER INFORMATION.—All information and
17 documentary material submitted pursuant to
18 this section and all information obtained by the
19 Attorney General in the course of any investiga-
20 tion or case with respect to a potential violation
21 of the antitrust laws by the health care coopera-
22 tive venture (other than information and mate-
23 rial described in subparagraph (A)) shall be ex-
24 empt from disclosure under section 552 of title
25 5, United States Code, and shall not be made

publicly available by any agency of the United States to which such section applies except in a judicial proceeding in which such information and material is subject to any protective order.

(5) WITHDRAWAL OF NOTIFICATION.—Any person who files a notification pursuant to this section may withdraw such notification before a publication by the Attorney General pursuant to paragraph (4).

Any person who is deemed to have filed a notification under paragraph (2)(A) shall be deemed to have withdrawn the notification if the certificate of review in question is revoked or withdrawn under section 5.

(6) NO JUDICIAL REVIEW PERMITTED.—Any action taken or not taken by the Attorney General with respect to notifications filed pursuant to this subsection shall not be subject to judicial review.

(b) PROTECTIONS FOR VENTURES SUBJECT TO NOTIFICATION.—

(1) IN GENERAL.—

(A) PROTECTIONS DESCRIBED.—The provisions of paragraphs (2), (3), (4), and (5) shall apply with respect to any action under the anti-trust laws challenging conduct within the scope of a notification which is in effect pursuant to subsection (a)(1).

1 (B) TIMING OF PROTECTIONS.—The pro-
2 tections described in this subsection shall apply
3 to the venture that is the subject of a notifica-
4 tion under subsection (a)(1) as of the earlier
5 of—

6 (i) the date of the publication in the
7 Federal Register of the notice published
8 with respect to the notification; or

9 (ii) if such notice is not published dur-
10 ing the period required under subsection
11 (a)(4), the expiration of the 30-day period
12 that begins on the date the Attorney Gen-
13 eral receives any necessary information re-
14 quired to be submitted under subsection
15 (a)(1) or any additional information re-
16 quired by the Attorney General under sub-
17 section (a)(3)(A).

18 (2) APPLICABILITY OF RULE OF REASON
19 STANDARD.—In any action under the antitrust laws,
20 the conduct of any person which is within the scope
21 of a notification filed under subsection (a) shall not
22 be deemed illegal per se, but shall be judged on the
23 basis of its reasonableness, taking into account all
24 relevant factors affecting competition, including, but

1 not limited to, effects on competition in relevant
2 markets.

3 (3) LIMITATION ON RECOVERY TO ACTUAL
4 DAMAGES AND INTEREST.—Notwithstanding section
5 4 of the Clayton Act, any person who is entitled to
6 recovery under the antitrust laws for conduct that is
7 within the scope of a notification filed under sub-
8 section (a) shall recover the actual damages sus-
9 tained by such person and interest calculated at the
10 rate specified in section 1961 of title 28, United
11 States Code, for the period beginning on the earliest
12 date for which injury can be established and ending
13 on the date of judgment, unless the court finds that
14 the award of all or part of such interest is unjust
15 under the circumstances.

16 (4) AWARD OF ATTORNEY'S FEES AND COSTS
17 OF SUIT.—

18 (A) IN GENERAL.—In any action under the
19 antitrust laws brought against a health care co-
20 operative venture for conduct that is within the
21 scope of a notification filed under subsection
22 (a), the court shall, at the conclusion of the
23 action—

24 (i) award to a substantially prevailing
25 claimant the cost of suit attributable to

1 such claim, including a reasonable attor-
2 ney's fee, or

3 (ii) award to a substantially prevailing
4 party defending against such claim the
5 cost of such suit attributable to such claim,
6 including reasonable attorney's fee, if the
7 claim, or the claimant's conduct during
8 litigation of the claim, was frivolous, un-
9 reasonable, without foundation, or in bad
10 faith.

11 (B) OFFSET IN CASES OF BAD FAITH.—

12 The court may reduce an award made pursuant
13 to subparagraph (A) in whole or in part by an
14 award in favor of another party for any part of
15 the cost of suit (including a reasonable attor-
16 ney's fee) attributable to conduct during the
17 litigation by any prevailing party that the court
18 finds to be frivolous, unreasonable, without
19 foundation, or in bad faith.

20 (5) RESTRICTIONS ON ADMISSIBILITY OF IN-
21 FORMATION.—

22 (A) IN GENERAL.—Any information dis-
23 closed in a notification submitted under sub-
24 section (a)(1) and the fact of the publication of
25 a notification by the Attorney General under

1 subsection (a)(4) shall only be admissible into
2 evidence in a judicial or administrative proceed-
3 ing for the sole purpose of establishing that a
4 party to a health care cooperative venture is en-
5 titled to the protections described in this sub-
6 section.

7 (B) ACTIONS OF ATTORNEY GENERAL.—

8 No action taken by the Attorney General pursu-
9 ant to this section shall be admissible into evi-
10 dence in any judicial or administrative proceed-
11 ing for the purpose of supporting or answering
12 any claim under the antitrust laws.

13 **SEC. 7. REVIEW AND REPORTS ON SAFE HARBORS AND**
14 **CERTIFICATES OF REVIEW.**

15 (a) IN GENERAL.—The Attorney General (in con-
16 sultation with the Secretary and the Chair) shall periodi-
17 cally review the safe harbors described in section 3, the
18 additional safe harbors designated under section 4, and
19 the certificates of review issued under section 5, and—

20 (1) with respect to the safe harbors described in
21 section 3, submit such recommendations to Congress
22 as the Attorney General considers appropriate for
23 modifications of such safe harbors;

24 (2) with respect to the additional safe harbors
25 designated under section 4, issue proposed revisions

1 to such activities and publish the revisions in the
2 Federal Register; and

3 (3) with respect to the certificates of review,
4 submit a report to Congress on the issuance of such
5 certificates, and shall include in the report a descrip-
6 tion of the effect of such certificates on increasing
7 access to high quality health care services at reduced
8 costs.

9 (b) RECOMMENDATIONS FOR LEGISLATION.—The
10 Attorney General shall include in the reports submitted
11 under subsection (a)(3) any recommendations of the At-
12 torney General for legislation to improve the program for
13 the issuance of certificates of review established under this
14 title.

15 **SEC. 8. RULES, REGULATIONS, AND GUIDELINES.**

16 (a) SAFE HARBORS, CERTIFICATES, AND NOTIFICA-
17 TIONS.—The Attorney General, with the concurrence of
18 the Secretary, shall promulgate such rules, regulations,
19 and guidelines as are necessary to carry out sections 3,
20 4, 5, and 6, including guidelines defining or relating to
21 relevant geographic and product markets for health care
22 services and providers of health care services.

23 (b) GUIDANCE FOR PROVIDERS.—

24 (1) IN GENERAL.—To promote greater cer-
25 tainty regarding the application of the antitrust laws

1 to activities in the health care market, the Attorney
2 General, in consultation with the Secretary and the
3 Chair, shall (not later than 1 year after the date of
4 the enactment of this Act), taking into account the
5 criteria used to designate additional safe harbors
6 under section 4 and grant certificates of review
7 under section 5, publish guidelines—

8 (A) to assist providers of health care serv-
9 ices in analyzing whether the activities of such
10 providers may be subject to a safe harbor under
11 sections 3 or 4; and

12 (B) describing specific types of activities
13 which would meet the requirements for a cer-
14 tificate of review under section 5, and summa-
15 rizing the factual and legal bases on which the
16 activities would meet the requirements.

17 (2) PERIODIC UPDATE.—The Attorney General
18 shall periodically update the guidelines published
19 under paragraph (1) as the Attorney General consid-
20 ers appropriate.

21 (3) WAIVER OF ADMINISTRATIVE PROCEDURE
22 ACT.—Section 553 of title 5, United States Code,
23 shall not apply to the issuance of guidelines under
24 paragraph (1).

1 **SEC. 9. ESTABLISHMENT OF HHS OFFICE OF HEALTH CARE**
2 **COMPETITION POLICY.**

3 (a) IN GENERAL.—There is established within the
4 Department of Health and Human Services an Office to
5 be known as the Office of Health Care Competition Policy
6 (hereafter in this section referred to as the “Office”). The
7 Office shall be headed by a director, who shall be ap-
8 pointed by the Secretary.

9 (b) DUTIES.—The Office shall coordinate the respon-
10 sibilities of the Secretary under this Act and otherwise as-
11 sist the Secretary in developing policies relating to the
12 competitive and collaborative activities of providers of
13 health care services.

14 **SEC. 10. DEFINITIONS.**

15 In this Act, the following definitions shall apply:

16 (1) The term “antitrust laws”—

17 (A) has the meaning given it in subsection
18 (a) of the first section of the Clayton Act (15
19 U.S.C. 12(a)), except that such term includes
20 section 5 of the Federal Trade Commission Act
21 (15 U.S.C. 45) to the extent such section ap-
22 plies to unfair methods of competition; and

23 (B) includes any State law similar to the
24 laws referred to in subparagraph (A).

25 (2) The term “Chair” means the Chair of the
26 Federal Trade Commission.

1 (3) The term “health benefit plan” means any
2 hospital or medical expense incurred policy or certifi-
3 cate, hospital or medical service plan contract, or
4 health maintenance subscriber contract, or a mul-
5 tiple employer welfare arrangement or employee ben-
6 efit plan (as defined under the Employee Retirement
7 Income Security Act of 1974) which provides bene-
8 fits with respect to health care services.

9 (4) The term “health care cooperative venture”
10 means any activities, including attempts to enter
11 into or perform a contract or agreement, carried out
12 by 2 or more persons for the purpose of providing
13 health care services.

14 (5) The term “health care services” means any
15 services for which payment may be made under a
16 health benefit plan, including services related to the
17 delivery or administration of such services.

18 (6) The term “medical self-regulatory entity”
19 means a medical society or association, a specialty
20 board, a recognized accrediting agency, or a hospital
21 medical staff, and includes the members, officers,
22 employees, consultants, and volunteers or commit-
23 tees of such an entity.

24 (7) The term “person” includes a State or unit
25 of local government.

1 (8) The term “provider of health care services”
2 means any individual or entity that is engaged in the
3 delivery of health care services in a State and that
4 is required by State law or regulation to be licensed
5 or certified by the State to engage in the delivery of
6 such services in the State.

7 (9) The term “Secretary” means the Secretary
8 of Health and Human Services.

9 (10) The term “specialty group” means a medi-
10 cal specialty or subspecialty in which a provider of
11 health care services may be licensed to practice by
12 a State (as determined by the Secretary in consulta-
13 tion with the certification boards for such specialties
14 and subspecialties).

15 (11) The term “standard setting and enforce-
16 ment activities” means—

17 (A) accreditation of health care practition-
18 ers, health care providers, medical education in-
19 stitutions, or medical education programs,

20 (B) technology assessment and risk man-
21 agement activities,

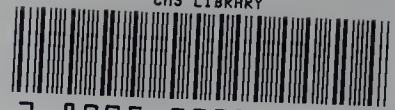
22 (C) the development and implementation of
23 practice guidelines or practice parameters, or

24 (D) official peer review proceedings under-
25 taken by a hospital medical staff (or committee

1 thereof) or a medical society or association for
2 purposes of evaluating the professional conduct
3 or quality of health care provided by a medical
4 professional.

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